UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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CONNETICS CORPORATION and CONNETICS AUSTRALIA PTY. LTD., Plaintiffs, v. AGIS INDUSTRIES (1983) LTD., Defendant.	05-5038 (HAA) **ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS** **JURY DEMANDED**

Defendant Agis Industries (1983) Ltd. ("Agis") (k/n/a Perrigo Israel Pharmaceuticals Ltd.), by and through the undersigned attorneys, answers the Complaint for

Patent Infringement of Plaintiff Connetics Corporation and Connetics Australia Pty. Ltd. (collectively, "Connetics") as follows:

Parties

COMPLAINT:

1. Connetics Corporation is a Delaware corporation having a principal place of business at 3160 Porter Drive, Palo Alto, California 94304.

ANSWER: Admitted.

COMPLAINT:

2. Connetics Australia Pty. Ltd. ("Connetics Australia") is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court, Rowville, Victoria 3168, Australia. Connetics Australia is a wholly-owned subsidiary of Connetics Corporation.

ANSWER: On information and belief, Agis admits that Connetics Australia has its principal place of business at 8 Macro Court, Rowville, Victoria 3178, Australia. Agis admits the remaining allegations of Paragraph 2.

COMPLAINT:

3. On information and belief, defendant Agis Industries (1983) Ltd. is an alien corporation organized under the laws of the State of Israel, having its principal place of business at 29 Lehi St., Bnei Brak 51200, Israel. According to the Agis Industries website, http://www.agisgroup.com/contact.asp, Defendant, through a wholly-owned and controlled subsidiary, has a regular and established place of business in this district located at 115 Route 46, West Building D, Mountain Lakes, New Jersey.

ANSWER: Agis admits that it is now known by the name Perrigo Israel Pharmaceuticals Ltd. ("Perrigo") and that it is a corporation organized under the laws of Israel, having a principal place of business at 29 Lehi St., Bnei Brak 51200, Israel. Agis further admits that Chemagis USA is organized under the laws of Delaware with a place of business located at 115 Route 46, West Building D, Mountain Lakes, New Jersey. Agis admits that Chemagis USA

and Perrigo Israel Pharmaceuticals Ltd. are both owned by Perrigo Co. Defendant denies the remaining allegations of Paragraph 3.

Jurisdiction and Venue

COMPLAINT:

4. This lawsuit is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 271(e)(2)(A), and 21 U.S.C. § 355, *et seq.*

ANSWER: Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Agis admits that Connetics' complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Connetics is entitled to such relief.

COMPLAINT:

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), 35 U.S.C. § 271(e)(4)(b) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Agis admits that this Court has subject matter jurisdiction over Connetics' infringement claim on the patent-in-suit. Agis denies the remaining allegations of Paragraph 5.

COMPLAINT:

6. There exists an actual, justiciable case or controversy between Connetics and Defendant, as to which Connetics requires: (i) a declaration of rights by this Court, and (ii) injunctive relief against Defendant, to prohibit Defendant from continuing to violate applicable laws and regulations to Connetics' irreparable injury, as complained of herein.

ANSWER: Agis admits that a justiciable controversy exists between Agis and Connetics as to Connetics' claim that Agis' ANDA product allegedly infringes unidentified

claims of U.S. Patent No. 6,126,920 ("the '920 patent"). Agis denies the remaining allegations of Paragraph 6.

COMPLAINT:

7. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(b)-(d) and/or 1400(b). Personal jurisdiction over Defendants [sic] comports with the United States Constitution and New Jersey's long-arm statute, N.J. Civ. Prac. R. 4:4-4.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Agis admits that venue is proper in this Court. Agis further admits that it is subject to personal jurisdiction in this judicial district.

Count I

COMPLAINT:

8. On October 3, 2000, United States Patent No. 6,126,920 ("the '920 Patent") entitled "METHOD OF TREATING A SKIN DISEASE WITH A CORTICOSTEROID-CONTAINING PHARMACEUTICAL COMPOSITION" was duly and legally issued to Medeva Europe PLC as assignee of the inventors named therein. A true and correct copy of the '920 Patent is attached to this Complaint as Exhibit 1.

ANSWER: Agis admits that the U.S. Patent and Trademark Office issued the '920 patent, entitled "METHOD OF TREATING A SKIN DISEASE WITH A CORTICOSTEROID-CONTAINING PHARMACEUTICAL COMPOSITION," on October 3, 2000, but specifically denies that the patent was duly or legally issued. Agis further admits, that, on its face, the '920 patent identifies Medeva Europe PLC as the assignee of the named inventors of the '920 patent, and that a copy of the '920 patent is attached to the Complaint.

COMPLAINT:

9. On or about June 25, 2003, Medeva Europe PLC assigned all rights, title and interest in the '920 Patent to Connetics Australia. Since that time, Connetics Australia has been and is the assignee and owner of the '920 Patent.

ANSWER: Agis admits that according to the U.S. Patent & Trademark Office website, Connetics Australia is the current assignee of the '920 patent. Agis has insufficient information to admit or deny the remaining allegations of Paragraph 9 and thus denies same.

COMPLAINT:

10. Connetics Corporation is the owner of an approved New Drug Application under Section 505(b) of the Federal Food Drug and Cosmetic Act (the "FFDCA" or the "Act"), 21 U.S.C. § 355(b)(1), for Olux® (clobetasol propionate) Foam 0.05%, which is covered by the '920 Patent.

ANSWER: Agis admits that according to the U.S. Food and Drug Administration's ("FDA") website, Connetics Corporation is the applicant for New Drug Application No. 21-142. Agis lacks sufficient information to admit or deny the remaining allegations of Paragraph 10, and thus denies same.

COMPLAINT:

11. Defendant has filed with the Food and Drug Administration an Abbreviated New Drug Application ("ANDA") pursuant to § 505(j) of the FFDCA, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale of clobetasol propionate foam 0.05%. The Defendant's ANDA included a certification pursuant to § 505(j)(2)(A)(vii)(IV) of the Act of Defendant's purported opinion that the '920 Patent is invalid, unenforceable, or not infringed by the submission of the Defendant's ANDA (a so-called "Paragraph IV Certification"). The Defendant's ANDA was assigned ANDA No. 77-763.

ANSWER: Admitted.

COMPLAINT:

12. On September 7, 2005, Connetics Corporation received from Defendant a written document titled "Notification Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act," in which Defendant informed Connetics that it had filed ANDA No. 77-763 containing a Paragraph IV Certification with respect to the '920 Patent. Connetics Australia received an identical communication on September 8, 2005.

ANSWER: Admitted.

COMPLAINT:

13. Because Defendant seeks approval of ANDA No. 77-763, and with such approval seeks to engage in the manufacture, use, offer for sale, or sale of a clobetasol propionate foam 0.05% covered by the '920 Patent before the expiration date of the '920 Patent, Defendant has infringed one or more claims of the '920 Patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Agis admits that filing an ANDA containing a paragraph IV certification to an Orange Book listed patent vests this Court with subject matter jurisdiction pursuant to 35 U.S.C. § 271(e)(2)(A) as to that patent. Agis admits that it filed an ANDA seeking approval to market a generic clobetasol propionate foam drug product. Agis denies the remaining allegations of Paragraph 13, including any implications that the patent-in-suit is infringed, valid, and/or enforceable.

COMPLAINT:

14. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the clobetasol propionate foam 0.05% described in ANDA No. 77-763 would infringe one or more claims of the '920 Patent.

ANSWER: Denied.

COMPLAINT:

15. Thus, Connetics is entitled to the relief provided by 35 U.S.C. § 271(e)(4).

ANSWER: Denied.

COMPLAINT:

16. Upon information and belief, Defendant's infringement of the '920 Patent is willful and deliberate with full knowledge of Connetics' rights in the '920 Patent, rendering this case exceptional under 35 U.S.C. § 285.

ANSWER: Denied.

AFFIRMATIVE DEFENSES

First Affirmative Defense

The manufacture, use, or sale of Agis' clobetasol propionate foam 0.05% product that is the subject of Agis' ANDA No. 77-763 has not infringed, does not infringe, and would not, if marketed, infringe any claim of the '920 patent.

Second Affirmative Defense

Plaintiffs' willful infringement allegations fail to state a claim upon which relief can be granted under controlling Federal Circuit case law.

Third Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal, including defenses of invalidity, under 35 U.S.C. §§ 101, 102, 103, and/or 112, and unenforceability.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Parties

1. On information and belief, Connetics Corporation is a Delaware corporation having a principal place of business at 3160 Porter Drive, Palo Alto, California 94304.

2. On information and belief, Connetics Australia Pty. Ltd. ("Connetics Australia") is a corporation organized and existing under the laws of the State of Victoria, Australia, having its principal place of business at 8 Macro Court, Rowville, Victoria 3178, Australia.

3. Agis Industries (1983) Ltd. ("Agis") (k/n/a Perrigo Israel Pharmaceuticals Ltd.), is a corporation organized and existing under the laws of Israel, with a principal place of business at 29 Lehi St., Bnei Brak 51200, Israel.

Background

A. FDA Approval of New Brand-Name Drugs.

4. The Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

5. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

6. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

7. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications ("ANDAs").

8. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients as the brand-name original.

9. Before 1984, a company that wished to make a generic version of an FDA-approved drug had to file an application containing new studies showing the already-approved

drug's safety and effectiveness. Preparing such an application was as time-consuming and costly as the original NDA.

10. In 1984, however, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

11. To receive approval of its ANDA, an applicant must show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

12. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

13. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

14. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

15. Upon receiving notice of the paragraph IV certification, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

16. Patent holders have a significant strategic incentive to file suit because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

17. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA. *Id.*

C. Agis' Clobetasol Propionate Foam ANDA.

18. Agis filed an ANDA (No. 77-763) with the FDA seeking generic approval for clobetasol propionate foam 0.05%.

19. Connetics is the approval holder of NDA No. 21-142.

20. Agis' ANDA references Connetics' NDA No. 21-142.

21. Because Agis seeks FDA approval to market its generic clobetasol propionate foam drug product before expiration of the patent that Connetics listed in the Orange Book, Agis' ANDA includes a paragraph IV certification to U.S. Patent No. 6,126,920 ("the '920 patent").

22. According to the U.S. Patent & Trademark Office website, Connetics Australia is the current assignee of the '920 patent.

23. Agis' ANDA products do not infringe any claim of the '920 patent.

Jurisdiction and Venue

24. Agis realleges and incorporates by reference the allegations of paragraphs 1-23.

25. Present, genuine, and justiciable controversies exist between Plaintiffs Connetics Corporation and Connetics Australia, and Defendant Agis regarding infringement of the '920 patent.

26. Subject matter jurisdiction over these counterclaims is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

27. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

Counterclaim I
Declaration of Non-Infringement of the '920 Patent

28. Agis realleges and incorporates by reference the allegations of paragraphs 1-25.

29. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that the claims of the '920 patent will not be infringed by the manufacture, use, offer for sale, or sale of Agis' clobetasol propionate foam drug product.

30. A present, genuine, and justiciable controversy exists between Plaintiffs Connetics Corporation and Connetics Australia and Defendant Agis regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of Agis' clobetasol propionate foam drug product would infringe the claims of the '920 patent.

31. The manufacture, use, offer for sale, or sale of Agis' clobetasol propionate foam drug product would not infringe the claims of the '920 patent.

32. Agis is entitled to a declaration that the manufacture, use, offer for sale, or sale of its clobetasol propionate foam drug product would not infringe the claims of the '920 patent.

JURY DEMAND

Agis demands a trial by jury.

REQUEST FOR RELIEF

WHEREFORE, Defendant Agis Industries (1983) Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs Connetics Corporation and Connetics Australia Pty. Ltd. as follows:

(a) declaring that Agis has not infringed U.S. Patent No. 6,126,920;

(b) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Agis its attorneys' fees, costs, and expenses in this action; and

(c) awarding Agis any further and additional relief as the Court deems just and proper.

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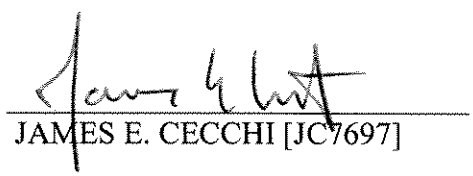
Dated: November 9, 2005

By: 
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

I hereby certify that the matter in controversy is not the subject matter of any other action pending in any court, or of any pending arbitration or administrative proceeding.

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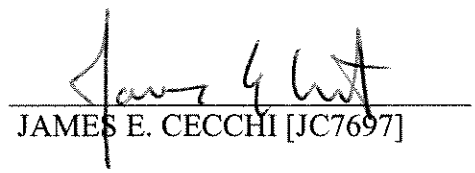
Dated: November 9, 2005

By: 
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CERTIFICATE OF SERVICE

I certify that the foregoing Agis Industries (1983) Ltd. Answer, Affirmative Defenses, and Counterclaims to Connetics Corporation and Connetics Australia Pty. Ltd.'s Complaint, was served this 9th day of November 2005, upon the following counsel as indicated below.

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